

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., NORTON
(WATERFORD) LTD., AND TEVA
PHARMACEUTICALS USA, INC.

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, AMNEAL IRELAND
LIMITED, AMNEAL
PHARMACEUTICALS LLC, AND
AMNEAL PHARMACEUTICALS INC.

Defendants.

Civil Action No. 2:23-cv-20964-
JXN-MAH

**CONSENTED TO MOTION OF THE FEDERAL TRADE COMMISSION
FOR PERMISSION TO FILE A MOTION ON MARCH 22, 2024
SEEKING LEAVE TO FILE AN AMICUS BRIEF**

The pending dispositive motions in this case raise significant competition issues with market-wide implications extending beyond the parties' private dispute. As an independent agency charged with protecting competition, the FTC has great interest and expertise in the consequences of improperly listing patents in the FDA's Orange Book, as Amneal alleges Teva did with the patents Teva asserts

in this litigation. Further, FTC staff has recent experience with specific patent listings at issue in this case.¹

Absent a local rule concerning the timing of amicus briefs, the FTC typically follows Rule 29 of the Federal Rule of Appellate Procedure and seeks to file briefs in support of a party seven days after that party's brief is filed. In this case, however, FTC staff requests additional time for staff and the Commission to consider whether to file a formal motion for leave as amicus curiae by March 22, 2024.²

Amneal and Teva consent to this motion. A proposed Order is attached.³

Respectfully submitted,

¹ In addition to enforcement and advocacy efforts concerning Orange Book abuse dating back two decades, the FTC issued a policy statement in September 2023 concerning the competitive consequences of improper Orange Book listing and the FTC's commitment to protecting consumers harmed by such practices. *See* FED. TRADE COMM'N. STATEMENT CONCERNING BRAND DRUG MANUFACTURERS' IMPROPER LISTING OF PATENTS IN THE ORANGE BOOK (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf. In November 2023, the FTC sent letters to ten brand drug manufacturers identifying what the FTC believes to be improper patent listings. Teva received one such letter and the patents at issue in this litigation were identified. *See* Press Release, Fed. Trade Comm'n, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book>.

² The Commission may only take action subject to a vote approved by the majority of participating commissioners. *See* 16 C.F.R. § 4.14(c).

³ This request is filed without a brief pursuant to Local Rule 7.1(d)(4) given the finite nature of the request and because no party has expressed opposition to this motion.

Ian Barlow
Deputy Director, Office of Policy Planning

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Counsel for Federal Trade Commission

Pursuant to Local Rule 101(f), the United States Attorney for the District of New Jersey is designated to receive service of all notices or papers in this action at the following address:

U.S. Attorney's Office
Civil Division
970 Broad Street, 7th Floor
Newark, NJ 07102

CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.2(14)(b)(1), I, Bradley J. Vettraino, hereby certify that the foregoing document was served on all counsel of record through the Court's CM/ECF system on March 5, 2024.

/s/ Bradley J. Vettraino
Bradley J. Vettraino